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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/782,652

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Knud T. Aundal

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MEDTRONIC, INC.  
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EXAMINER

PANI, JOHN

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/782,652	<b>Applicant(s)</b> AUNDAL ET AL.	
	<b>Examiner</b> JOHN PANI	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-38 is/are pending in the application.
- 4a) Of the above claim(s) 8-14, 19-30, 34-36 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 15, 16, 18, 31-33 and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 5 and 33 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 1 and 31 already include the only limitation of claims 5 and 33.
2. Claim 17 is objected to because of the following informalities: The claim has been canceled but the text of the claim remains in the claims as presented. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
4. Claims 1, 4, 5, 15, 16, 18, 31-33 and 37 rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,318,533 to Adams et al. ("Adams") in view of US Pat. No. 4,566,480 to Parham ("Parham").

In reference to Claims 1, 5, 31, and 33

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Adams teaches a catheter system comprising: a catheter (200) defining an internal lumen (204); a balloon (202) mounted on the catheter, the balloon defining an internal chamber in fluid communication with the lumen; a charging mechanism/means for charging including a closed reservoir (14, 20, closed when 26 is closed), a passage (portion of 26 on distal side of stopcock/valve which connects to 200, see Fig. 1), and an actuator (16, 18) to charge and discharge the balloon with at least a portion of a volume of fluid contained in the closed reservoir, wherein the closed reservoir is in fluid communication with the lumen via the passage (col. 3 lines 45-49) and substantially sealed from an environment outside the catheter system (see Fig. 1); and a pressure sensor/means for sensing a pressure (28) in fluid communication (via 20, 26 etc.) with the lumen to sense a pressure of the fluid; and a sensor body (10, 24, 26) having a housing (the exterior of each of these components) that houses the sensor, the reservoir, and the charging mechanism, and a catheter body (most proximal section of 200 which connects to 26) defining a channel for fluid communication between the lumen and the sensor (some channel in the connection is necessary for the device to work). Adams further teaches a fitting (stopcock 26 has some sort of fitting which is used to connect itself to the catheter; col. 3 lines 48-51) configured to couple a catheter body coupled to a proximal end of the catheter to the sensor body, but it is unclear whether the fitting is housed in the sensor body.

Parham teaches a medical stopcock which includes female luer connectors (see Fig. 2). Adams teaches that the catheter can be attached with luer connectors. It would have been obvious to one having ordinary skill in the art at the time of the invention to

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have made the connection between the catheter and the stopcock a female luer connector on the stopcock because it is a well-known medical connection as suggested by Parham and Adams, and because there are only male and female luer fittings, and one of ordinary skill of the art would be expected to choose either of the two. A female luer connector connects to a male due to the friction between the female's inner wall and the male's inner wall. Thus, this inner wall is interpreted herein as the claimed "fitting", and this inner wall is housed within the "sensor body" as defined above with regards to the Adams reference.

In reference to Claims 4 and 32

The catheter system of claims 1 and 31 (see above) further comprising a monitoring device (100) to monitor the sensed pressure.

In reference to Claims 15 and 16

The catheter system of claim 1 (see above) wherein the actuator includes a piston and a screw, wherein the distal end of the piston ("piston") and screw (16) are movable to drive a portion of the fluid out of the reservoir and into the lumen to charge the balloon (see col. 3 lines 29-45).

In reference to Claim 18

The catheter system of claim 1 (see above) wherein the pressure sensor comprises a strain gauge (col. 6 lines 9-13).

In reference to Claim 37

A sensor body (10, 24, 26) for a balloon catheter system, the sensor body comprising: a first fitting (26) to couple the sensor body to a catheter body; a second

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fitting (80) to couple the sensor body to a monitor (100); a charging mechanism including a closed reservoir (14, 20, closed when 26 is closed), a passage (portion of 26 on distal side of stopcock/valve which connects to 200, see Fig. 1), and an actuator (16,18) to charge and discharge a balloon mounted on the catheter via a lumen (204) with at least a portion of a volume of fluid contained in the closed reservoir, wherein the closed reservoir is in fluid communication with the lumen via the passage (col. 3 lines 45-49) and substantially sealed from an environment outside the balloon catheter system (see Fig. 1); and a housing (exterior of 10, 24, and 26), wherein the second fitting and the closed reservoir (see Fig. 2), the passage, and the actuator of the charging mechanism (see Fig. 1) are enclosed within the housing. It is unclear whether the first fitting is housed in the sensor body.

Parham teaches a medical stopcock which includes female luer connectors (see Fig. 2). Adams teaches that the catheter can be attached with luer connectors. It would have been obvious to one having ordinary skill in the art at the time of the invention to have made the connection between the catheter and the stopcock a female luer connector on the stopcock because it is a well-known medical connection as suggested by Parham and Adams, and because there are only male and female luer fittings, and one of ordinary skill of the art would be expected to choose either of the two. A female luer connector connects to a male due to the friction between the female's inner wall and the male's inner wall. Thus, this inner wall is interpreted herein as the claimed "first fitting", and this inner wall is housed within the housing of the "sensor body" as defined

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above with regards to the Adams reference. In this combination, the lumen of the female luer fitting could be interpreted as "the passage".

5. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams in view of US Pat. No. 4,715,378 to Pope et al. ("Pope").

Adams teaches the device of claim 1 (see above) but does not explicitly disclose that the fluid is either a liquid or a gas. Pope teaches a balloon catheter that is inflated with either gas or liquid (col. 1 lines 9-11). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the device of Adams by filling the reservoir with either gas or liquid as the type of fluid as taught by Pope because it is obvious to use a known suitable material to predictably accomplish a known desired task.

6. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams in view of US Pat. No. 5,195,957 to Tollini et al ("Tollini").

Adams teaches the device of claim 1 (see above) but does not explicitly teach a seal member disposed between the sensor and the catheter body wherein the seal member includes a deformable surface that deforms under compression upon engagement of the sensor body and the catheter body to produce a fluid seal about the channel.

Adams does teach that a Luer stopcock/valve is used to attach the inflation device to the catheter (see col. 3 lines 45-50). Tollini teaches placing an O-ring on a female Luer member to engage between the shoulder and rim of the collar on the male Luer member, thereby providing a better seal (see at least Abstract). It would have been

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obvious to one having ordinary skill in the art at the time of the invention to have modified the device of Adams by including an O-ring between male and female Luer connectors in order to provide a better seal as taught by Tollini.

### ***Response to Arguments***

7. Applicant's arguments with respect to claims 1, 31, and 37 regarding Adams lack of teaching a sensor housing that houses a fitting configured to couple a catheter body to the sensor body have been considered but are moot in view of the new ground(s) of rejection.

8. Applicant's remaining arguments filed 3/3/2009 have been fully considered but they are not persuasive. Applicant appears to have misinterpreted the Examiner's application of the Adams reference. The Examiner's assertion was not that a single one of element 10 or element 24 or element 26 was the sensor body, but that together they formed the sensor body, because between all of these components, the sensor is sealed off from the outside world. In other words, the exterior of the device which includes each of these components form a continuous exterior which encloses/houses the sensor, and therefore this continuous exterior is a housing and is fairly interpreted as the "sensor body". If Applicant is asserting that "sensor body" has a special definition which means only the exterior of the pressure sensor, etc., the Examiner notes that in each drawing of the instant application, the pressure sensor is depicted as reference number 32, and that 32 is not depicted as housing each of the other claimed portions, and that therefore this special definition would not be supported by the originally filed



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disclosure. Further, originally filed claim 5 is considered evidence that the sensor body can include sections of the device that are not contained within the sensor itself. The Examiner further submits that the interior wall of a luer fitting (which would be part of the stopcock of Adams as modified by Parham) is housed by the exterior, and that the exterior is a housing, particularly in light of one common definition of housing as "anything that covers or protects" (Dictionary.com Unabridged Based on the Random House Dictionary, © Random House, Inc. 2009.).

### ***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN PANI whose telephone number is (571)270-1996. The examiner can normally be reached on Monday-Friday 7:30 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JP 6/10/09

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736